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Solicitation of Public Review and Comment of Research Protocol:
A Multicenter Randomized Dose Response Study of the safety, Clinical and Immune
Response of Dryvox Administered to Children 2 to 5 years of age.
Dockets Management Branch (HFA-305)
Docket No.02N-0466
Food and Drug Administration

To Whom It May Concern:

I am writing to you today with concern of the study, A Multicenter Randomized
Dose Response Study of the Safety, Clinical and Immune Response of Dryvox
Administered to Children 2 to 5 years of age.

I learned of this study through several articles of which I have recently read. With
the information I have attained from these articles, I have come to the conclusion that for
many reasons, this study should not be done. In this study, Forty children ages two to five
years old will be taken out of schools and daycares for one month and be administered
the smallpox vaccine. Throughout the month, scientists will be studying these children to
see if diluted doses of this vaccine will be sufficient in preventing the Smallpox Virus.
The children will be expected to have a bandage covering the injection site for the whole
month without touching it. If the child by any chance touches the injection site, and then
touches his or her mouth, eye, or another person, that child, and the other person could be
infected with the actual Smallpox virus. I feel that this plan to test the vaccine in young
children is severely flawed. There are many other issues dealing with the safety, health
and the well being of the children that must be taken into greater consideration.

One reason why this study should not be carried out without more research and
information is that this study will affect these children in all aspects of their lives for the
whole month. This study is completely unethical. These children don't understand the
risks and side affects this vaccine may have on them if they do not follow doctor's
instructions. There are serious risks involved in this study, and if anything goes wrong,
death can be the result. "It may be unethical to test in healthy children a vaccine that
could cause a life threatening reaction when the children probably won't benefit from it -
unless a bio-terrorist attacks with smallpox." This quote was mentioned in an article
written by Lauran Neergaard, AP Medical Writer. The reason why this testing was even
taken into thought is because President Bush feels that terrorists might have gotten a hold
of the virus and could use it against us in an attack. There have been no Smallpox
outbreaks in the world since the early 1970's, and if terrorists never attack with the
smallpox virus, then this whole study would have been a foolish waste since we will not
need to treat Smallpox unless this happens.

Another reason why we should not test without more research is that the
children's social and academic progress will be put on hold for a whole month. The ages

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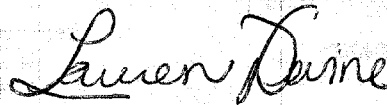
of 4 and 5 especially, are crucial in the development of a young child's social and academic progress. I have not read anything about what the FDA proposes to do in regards to education and socialization of the children. Are the children going to be isolated from all friends and family for the whole month, are they going to be kept in hospitals, who is going to care for them while their parents go to work, how will these children stay caught up with school. These are just a few of the many questions I have as well as the rest of the public. If I were to consider participating my child in a study with so many risks I would need to know all of the facts and technicalities of it.

Though there are many opposing arguments to the Smallpox vaccine, we may also benefit from this research in the future. If by chance we were to have a bio-terrorist attack, we would know how this vaccine affected children and we would be prepared. Also it would put parents at ease about giving their children the vaccine because they would now all of the side affects and risks that go along with it. Dr. Julia McMillan of Johns Hopkins University, a spokeswoman for the American Academy of Pediatrics said, "I would certainly want these trials to be conducted before I would want my child to be vaccinated." But on the other hand, to avoid even having to test on children, if we are hit with an attack, we could administer the vaccine through Ring Vaccination. "Ring vaccination controls an outbreak by vaccinating and monitoring a ring of people around each infected individual" (American Academy of Pediatrics)

In conclusion, I believe that the study of vaccinating forty children ages two to five is highly unethical, this study has many unanswered questions of what will be done about the children's social and academic progress for that month, we will not need to use this information unless there is a bio-terrorist attack, and there are also other alternatives if we do end up having a Smallpox outbreak. As you can see, there are still many flaws in this plan that need to be looked over. Instead of putting these children's lives at risk please take my thoughts into consideration in revising the plan to test the Smallpox vaccine on these children.

Sincerely,

Lauren Devine

A handwritten signature in cursive script that reads "Lauren Devine". The signature is written in dark ink and is positioned below the printed name.